

# Surveillance of HIV, Hepatitis B and Hepatitis C, and related (risk) behavior among hard drug users under addictive care at Mondriaan centre in Heerlen

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To assess the prevalence of HIV, hepatitis C and B, and (related) risk behavior among hard drug users in care at Mondriaan carecentre for addiction in Heerlen.

<b>Ethical review</b>	Not approved
<b>Status</b>	Will not start
<b>Health condition type</b>	Immunodeficiency syndromes
<b>Study type</b>	Observational non invasive

## Summary

### ID

NL-OMON33271

### Source

ToetsingOnline

### Brief title

Surveillance of HIV, hepatitis B and C among hard drug users

### Condition

- Immunodeficiency syndromes
- Viral infectious disorders
- Lifestyle issues

### Synonym

AIDS, Hepatitis, HIV, infectious diseases, jaundice

### Research involving

Human

## Sponsors and support

**Primary sponsor:** RIVM

**Source(s) of monetary or material Support:** Ministerie van OC&W

## Intervention

**Keyword:** addictive care, hard drug users, Heerlen, infectious diseases screening

## Outcome measures

### Primary outcome

The primary outcome of interest is to assess in the prevalence of viral infectious diseases (HIV, hepatitis C and hepatitis B) among hard drug users in care at Mondriaan carecentre for addiction in Heerlen.

### Secondary outcome

Secondary outcomes encloses understanding of potential associations for infectious diseases, and (related) risk factors like drug and sexual behavior, demographics, mobility of addicts, detention, sexual transmitted diseases and the use of Methadone.

## Study description

### Background summary

Since 1994, the national institute of public health and the environment (RIVM) has conducted several HIV surveys among (injecting) hard drug users in several cities in the Netherlands. These surveys have been accomplished under the authority of the Ministry of Health, Welfare and Sports with the purpose to increase the knowledge of the HIV epidemic among injecting drug users in the Netherlands.

In 2001, the Advisory Council on Health Research (RGO) betrayed advice about HIV surveillances in the Netherlands. One suggestion was to precede HIV surveys among (injecting) hard drug users every 5 years in different regions within the country. Moreover, the RGO also recommended expanding surveys toward specific risk groups, like sex workers and migrants from HIV endemic countries. The most

recent survey among IDU was in 2002 in Rotterdam.

In 2007, the methods and objectives of HIV surveys among risk groups have been evaluated by the RIVM. One of the main recommendations of this evaluation was to improve utilization of regular surveillance systems to facilitate monitoring of

national HIV data among these groups.

Data of the HIV surveys and data of the Amsterdam Cohort Studies show that injecting drug use has decreased and is less popular nowadays. National registration data of HIV in care at one of the HIV treatment centers showed that the contribution of hard drug users to the general HIV epidemic has decreased in the last years. In 1996, only 1% of all newly diagnosed HIV patients within HIV treatment centers could be attributed to injecting drug use, compared to 11% in 1992. However, results on HIV prevalence from HIV surveys show high prevalences.

Regular infectious diseases screening among hard drug users in care for their addiction in different regions in the Netherlands is needed to enlarge insights in the prevalence and its risk factors of viral infectious diseases among this group. Therefore, data from the questionnaires will be matched with data on infectious diseases screening from already existing registration systems among hard drug users in care in Mondriaan carecentre in Heerlen.

Data from studies and available data from registration systems of infectious diseases among hard drug users is reported at a yearly basis to the European Monitoring Centre for Drugs and Drug Addiction (EMCDDA) in Lisbon by the Focal Point for Netherlands (Trimbosinstituut).

## **Study objective**

To assess the prevalence of HIV, hepatitis C and B, and (related) risk behavior among hard drug users in care at Mondriaan carecentre for addiction in Heerlen.

## **Study design**

The number of people using hard drugs in Heerlen is currently estimated to be 800. About 400 are in care at the Mondriaan care centre for addiction and therefore known, the other part is unknown. Presently, approximately 300 hard drug users are in active follow-up who are voluntary screened for HIV, Hepatitis B & C at a yearly basis since 2003.

a) Database of patients of Mondriaan care centre

The anonymised database of patients will be used to conduct descriptive analyses (for example number of drug users screened and corresponding results, etc.) This electronic database however, is not fully updated since regular health care is using written medical files. Therefore, due to the incompleteness of this database, we will include an additional form filled in by the

nurse/doctor on the infectious disease status of the participant (see protocol).

#### b) Data collection by the questionnaire study

Hard drug users in care at Mondriaan addiction centre will be approached at the following locations by the nurse/doctor for participating in the questionnaire study:

- methadone substitution treatment: 80 drug users will be included in the study
- heroin distribution: 20 drug users will be included in the study

The nurse/doctor will start by explaining the objectives, the procedures and the content of the study. The information letter will be handed out and discussed to the drug user before signing written informed consent. If the drug user decides to participate the questionnaire is handed out and the nurse/doctor fills in the form. After completion of the questionnaire the participant receives 10 euros payment.

### **Study burden and risks**

During the supply of methadone and heroin at Mondriaan centre, hard drug users will be asked to participate in the questionnaire study. The study will be explained by a healthcare worker (doctor or nurse), written informed consent will be asked. They will be asked to fill out the questionnaire themselves. Filling out the questionnaire will take approximately 20 minutes.

## **Contacts**

### **Public**

RIVM

Postbus 1  
3720 BA BILTHOVEN  
Nederland

### **Scientific**

RIVM

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3720 BA BILTHOVEN  
Nederland

## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

- Individuals aged 18 and above
- Individuals who are under care at Mondriaan outpatient clinic for drug addicts in Heerlen
- Individuals who have used hard drugs at least once a week throughout the last 6 months. Hard drugs are defined as heroin, coke, opium, methadone, LSD, amphetamine (speed), or XTC
- Both injecting and non-injecting hard drug users
- Individuals with a signed written informed consent for participation in the study

### Exclusion criteria

- Individuals under the age of 18 years
- Individuals without written informed consent
- Individuals who have participated in the study before
- Individuals who have not used hard drugs more than once a week throughout the last 6 months

## Study design

### Design

**Study type:** Observational non invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Prevention

## Recruitment

NL  
Recruitment status: Will not start  
Enrollment: 100  
Type: Anticipated

## Ethics review

Not approved  
Date: 07-04-2009  
Application type: First submission  
Review commission: METC Universitair Medisch Centrum Utrecht (Utrecht)

## Study registrations

### Followed up by the following (possibly more current) registration

No registrations found.

### Other (possibly less up-to-date) registrations in this register

No registrations found.

## In other registers

Register	ID
CCMO	NL27393.041.09